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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/052,889

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Emil A. Tanagho

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,889

Applicant(s)

TANAGHO ET AL.

Examiner

Paul B. Prebilio

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Applicant elected Group III, claim 24 for prosecution. Because of the amendment filed along with the election, no claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention because the only remaining claims are drawn to the elected invention. Election was made **without** traverse in Paper No. 5 filed December 11, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8, and 10 of U.S. Patent No. 6,371,992. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are so similar that they are considered obvious over each other. This is due to the fact that the bladder (patented claims) and the ureter or urethra as presently claim, are from the same tract

Art Unit: 3738

and connected to each other. For this reason, it would have been obvious to make a matrix from one or the other because of their similarity in structure and function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bishopric et al (US 5,855,620) or Goldstein (US 5,632,778) or Abraham et al (US 5,993,844) in view of Gregory (US 5,990,379). Bishopric (see column 3, lines 45-68) or Goldstein (see column 3, lines 11-20 and column 5, line 10 to column 6, line 52) or Abraham (see column 3, line 53 to column 5, line 51) all disclose producing intact collagen and elastin matrixes but not of ureter or urethra tissue as claimed. However, Gregory teaches that it was known to make intact elastin matrixes out of ureters; see *supra*. Therefore, it is the Examiner's position that it would have been obvious to make ureter tissue matrixes in the Bishopric or Goldstein or Abraham so that the particular tissue could be replaced in a recipient who needs such.

Regarding claims 26-28, the claimed properties would inherently be present because Gregory produces the same material as that claimed.

Response to Arguments

In response to the arguments filed in response to the previous Office action that Gregory ('379) fails to disclose an implant without a support structure, the Examiner

Art Unit: 3738

disagrees and directs Applicants to column 5, line 66 to column 6, line 5 where such an embodiment is disclosed. However, the Applicants' argument that Gregory ('379) fails to disclose an intact matrix of both collagen and elastic fibers was considered persuasive. In particular, the embodiment of Gregory that is drawn to intact matrixes of elastic fibers (i.e. elastin) appear to remove all the collagen; see Example 3 on column 11, especially lines 55-58. Other embodiments with elastin and collagen are disclosed, but the matrixes of both the collagen and elastin do not appear intact; see column 4, lines 16-39. For this reason, the Gregory Section 102 rejection has been withdrawn, but there may be support for a Section 102 rejection based upon the incorporated prior art; see column 4, lines 16-39.

With regard to the traversal of the Probst rejection, the Examiner has withdrawn the rejection based upon the unequivocal declaration that the presently claimed invention was invented by the present inventors; see the "Declaration of Inventorship" filed July 27, 2004.

Applicants also tried to use a 37 CFR 1.131 declaration to overcome the Section 103 Abraham rejection, but this was considered insufficient. In particular, using the Probst publication as evidence of earlier invention goes against a court decision on the matter in *In re Costello*; see MPEP 716.10, the paragraph immediately preceding the examples (this section is incorporated herein by reference). In addition, the claimed invention is not disclosed by the Probst article in that it does not fall within the claimed scope; see MPEP 715.02 which is incorporated herein by reference. For this additional reason, the declaration is considered insufficient.

Next, Applicants traverse the combination of Bisphoric and Goldstein with Gregory because they are not drawn to the same tissues as the secondary reference of Gregory. This is considered unpersuasive because of the fact that Bisphoric, Goldstein, and Gregory all disclose treatment of vascular tissues. This provides the nexus between the primary and secondary references and suggests that there would be no unreasonable expectation of success as argued. Furthermore, the argument that Gregory uses a method that removes collagen is considered unpersuasive because one cannot show unobviousness by arguing references individually; see MPEP 2145 (IV) which is incorporated herein by reference.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

Art Unit: 3738

applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738